AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	POMBILITI (cipaglucosidase alfa-atga)	Page:	1 of 2
Effective Date:	2/10/2024	Last Review Date:	12/1/2023

Applies to:	☒ Illinois	☐ Florida	☐ New Jersey
	☒ Maryland	☒ Florida Kids	☒ Pennsylvania Kids
	☐ Michigan	☒ Virginia	☐ Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Pombiliti under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

Pombiliti is indicated, in combination with Opfolda, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing greater than or equal to 40 kg and who are not improving on their current enzyme replacement therapy (ERT).

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Pombiliti

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   Acid alpha-glucosidase enzyme assay or genetic testing results supporting diagnosis.
B. Continuation requests:
   Chart notes documenting a positive response to therapy (e.g., improvement, stabilization, or slowing of disease progression for motor function, walking capacity, respiratory function, muscle strength).

Criteria for Initial Approval:

Late-onset Pompe disease

Authorization may be granted for treatment of late-onset Pompe disease when ALL the following criteria are met:

1. Member is 18 years of age or older.
2. Member weighs greater than or equal to 40 kg.

3. Diagnosis was confirmed by enzyme assay demonstrating a deficiency of acid alpha-glucosidase enzyme activity or by genetic testing.
4. The requested medication will be taken in combination with Opfolda (miglustat).
5. Member is not improving on current enzyme replacement therapy (ERT) (e.g., Lumizyme, Nexviazyme).

Continuation of Therapy
Late-onset Pompe disease
Authorization may be granted for continued treatment in members requesting reauthorization when the following criteria is met:

A. Member is responding to therapy (e.g., improvement, stabilization, or slowing of disease progression for motor function, walking capacity, respiratory function, or muscle strength).

Approval Duration and Quantity Restrictions:

Initial and Renewal: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Pombiliti [package insert]. Philadelphia, PA: Amicus Therapeutics US, LLC; September 2023.